What is claimed is:

1. A composition for controlled release of a bioactive substance, comprising:

a. a coacervate;

b. a bioactive substance incorporated in said coacervate; and

c. a delivery agent incorporated in said coacervate,

wherein said bioactive substance is a nucleic acid.

2. The composition of claim 1, wherein said coacervate is a microsphere.

3. The composition of claim 2, wherein said microsphere comprises at least an anionic molecule in addition to said nucleic acid and a cationic molecule.

4. The composition of claim 3, wherein said nucleic acid is a transfer vector.

5. The composition of claim 4, wherein said transfer vector includes a transgene.

6. The composition of claim 4, wherein said delivery agent is at least one of the following: amphiphilic molecule, lipid or polylysine.

7. The composition of claim 4, wherein said microsphere is crosslinked by a crosslinking agent.

~~8. The composition of claim 4, wherein said crosslinking agent comprises a metal cation.~~

9. The composition of claim 8, wherein said metal cation comprises calcium.

10. The composition of claim 4, wherein said anionic molecule is alginate.

11. The composition of claim 4, wherein said cationic molecule is gelatin.

12. The composition of claim 4, wherein said cationic molecule is gelatin, and wherein said anionic molecule is alginate.

13. The composition of claim 4, wherein said transfer vector comprises at least one regulatory element.

14. The composition of claim 13, wherein said regulatory element is a promoter.

15. The composition of claim 4, wherein said transfer vector comprises an expression vector.

16. The composition of claim 4, wherein said transfer vector comprises a viral vector, said delivery agent is a virus, and said virus comprises at least about five percent by weight of said microsphere.

17. The composition of claim 15, wherein administration ~~of said microsphere to a patient results in~~ controlled release of said expression vector.

18. The composition of claim 17, wherein said delivery agent facilitates intracellular delivery of said expression vector in said patient.

19. The composition of claim 18, wherein said expression vector produces a recombinant protein in said patient.

20. The composition of claim 19, wherein said recombinant protein is an antigen.

21. The composition of claim 4, wherein said microsphere is lyophilized.

22. The composition of claim 17, wherein said microsphere further comprises a second expression vector.

23. The composition of claim 1, wherein said nucleic acid is a viral vector, and said delivery agent is a virus.

24. The composition of claim 3, wherein said nucleic acid is a viral vector, and said delivery agent is a virus of said viral vector.

25. The composition of claim 24, wherein said viral vector contains a transgene.

26. The composition of claim 24, ~~wherein~~ said viral vector contains nucleic acid encoding a recombinant gene product.

27. The composition of claim 26, wherein said gene product is an antigen.

28. The composition of claim 24, wherein said viral vector and said virus of said viral vector are one of the following: recombinant retroviruse, adenovirus, adeno-associated virus, or herpes simplex virus-1.

29. A gene delivery system for transducing cells of a host, comprising: a microsphere encapsulating at least a nucleic acid and a delivery agent for facilitating intracellular delivery of said nucleic acid, wherein upon administration of said microsphere to a host, controlled release of said coacervate results in transduction of cells of said host by said nucleic acid.

30. A method for delivering a nucleic acid to a host, comprising: administering to a host a composition comprising a coacervate, wherein:

i. said coacervate incorporates a nucleic acid contained in a transfer vector having at least one regulatory element;

ii. said coacervate comprises a cationic molecule and an anionic molecule other than said nucleic acid;

iii. said coacervate is a microsphere; and,

iv. said coacervate incorporates a delivery agent,

wherein said administration of said composition results in controlled release of said transfer vector in vivo.

31. The method of claim 30, wherein said transfer vector is a viral vector, said delivery agent is a virus of said viral vector, and said viral vector is enveloped in said virus.

32. The method of cla[redacted]l, wherein said controlled release of sa[redacted]rus produces a therapeutically beneficial response in said host.

33. The method of claim 31, wherein said virus facilitates intracellular delivery of said viral vector.

34. The method of claim 31, further comprising administering to said host said coacervate as a pharmaceutical composition.

35. A kit containing a gene delivery system, comprising microspheres and instructions for using said microspheres, wherein said microspheres are comprised of a cationic molecule and an anionic molecule and said microspheres encapsulate a virus.

36. A coacervate microsphere for sustained release of a virus, comprising: a coacervate of gelatin and alginate having a virus incorporated therein.

37. The coacervate microsphere of claim 36, wherein said virus comprises a recombinant virus or an engineered natural virus.

38. A method for the sustained release of a virus to a target site, comprising: providing to the target site a coacervate microsphere comprising a coacervate of gelatin and alginate having a virus incorporated therein.

39. The use of a coacervate of cationic and anionic molecules in the manufacture of a medicament to transfect host cells <u>in vivo</u>, wherein a recombinant virus is encapsulated in said coacervate.

40. A method for preparing a gene delivery system, comprising:

a. preparing a first solution of a cationic molecule and a second solution of an anionic molecule;

b. adding to either said first solution or said second solution a nucleic acid; and adding to either said first solution or said second solution a delivery agent;

c. combining said first solution and said second solution to form a third solution; and,

d. isolating coacervates formed from a portion of said cationic molecule and a portion of said anionic molecule from said third solution,

wherein said coacervates encapsulates at least a portion of said nucleic acid and said delivery agent.

41. The method of claim 40, wherein substantially all of said coacervates are microspheres.

42. The method of claim 41, wherein said nucleic acid comprises a viral vector, said delivery agent comprises a virus particle corresponding to said viral vector, and said viral vector is encapsulated in said virus particle.

43. The method of claim 41, further comprising mixing said third solution to form said coacervates.

44. The method of claim 42, wherein said first and said second solution are substantially aqueous.

45. The method of claim 42, further comprising one or more processing step for preparing said microspheres for administration to a host, wherein said step does not impair the controlled release of said virus particle from said microsphere.

46. The method of claim 41, further comprising lyophilizing said microspheres after said isolation.

47. A coacervate microsphere for transfection and expression of a recombinant protein prepared by the process comprising:

a. in any order:

i. adding a cationic molecule to a first aqueous solution;

ii. adding a anionic molecule to a second aqueous solution; and,

iii. adding to either said first or said second solution a virus comprising a viral vector comprising a nucleic acid encoding a recombinant protein and at least one regulatory element;

b. mixing said [redacted] and second solution together to form a [redacted] cervate microsphere of said cationic molecule and said anionic molecule encapsulating said virus; and,

c. isolating said coacervate microspheres,

wherein release of said virus from said coacervate and transfection of cells by said virus in vivo or in vitro results in expression of said recombinant protein.

48. A gene delivery system for transfecting a cell with an expression vector, comprising:

a. encapsulation means for encapsulating an expression vector;

b. delivery means for facilitating intracellular delivery of said encapsulated expression vector;

wherein said encapsulation means comprises a coacervate, and wherein release of said encapsulated expression vector from said encapsulation means transfects a cell.